

Notice of Allowability

Application No.

09/899,026

Examiner

Humera N. Sheikh

Applicant(s)

STAMM ET AL.

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11 March 2005.
2. ☒ The allowed claim(s) is/are 162-187, 189-199, 201-229 and 231-248.
3. ☒ The drawings filed on 06 July 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/005,128.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 02/23/05, 6-25-04, 6-16-04 and 3-30-04
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

DETAILED ACTION

Status of the Application

Receipt of the Supplemental Amendment and Response under 37 C.F.R. §1.111 and Applicant's Arguments/Remarks, filed 03/11/05, the Amendment and Response under 37 C.F.R. §1.111, the Information Disclosure Statement (IDS), the request for extension of time (3 months) and the Affidavit/Declaration under 37 C.F.R. §1.132, all filed 02/23/05 is acknowledged.

Claims 162-187, 189-199, 201-229 and 231-248 are pending. Claims 162, 192 and 209 have been amended. New claims 240-248 have been added. Claims 1-161, 188, 200 and 230 have been cancelled.

Allowable Subject Matter

Claims 162-187, 189-199, 201-229 and 231-248 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Boyer US 4,800,079; Kerc *et al.* US 6,042,847 ; Mughal *et al.* US 4,524,060 & Klimesch *et al.* US 5,073,379) do not disclose nor fairly suggest a micronized fenofibrate composition having a dissolution profile of at least 75% in 30 minutes in a dissolution medium constituted by either water with 2% by weight polysorbate 80 or a dissolution medium which is 0.025M sodium lauryl sulfate. Rather, the prior art teaches a slower dissolution profile (*i.e.*, 65% taught by Boyer) and uses a different dissolution medium than that instantly claimed. The instant invention is an enhancement over prior art formulations

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because it provides for high bioavailability of fenofibrate through improved dissolution, thus reducing the dose required to be administered. The instant formulation provides for increased bioavailability over very short periods of time as compared with formulations of the prior art. In an interview held on 11/09/04 with Applicant's representative, suggestions were made to include the limitation of 'at least 75% in 30 minutes' recited in claim 188 into generic claim 162. An agreement was reached during the interview that the prior art did not teach nor suggest a dissolution profile of 'at least 75% in 30 minutes' nor did the prior art teach or suggest a dissolution medium as instantly claimed. Applicant's representative adopted the Examiner's suggestions to incorporate the dissolution profile ('at least 75% in 30 mins.') of claim 188 into claim 162. Accordingly, the instant application is rendered non-obvious and patentable over the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh 

Patent Examiner

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April 14, 2005


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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